K112696

510(k) Summary

APR 18 2012

Manufacturer:

Qualgenix
87 Carmel Hill Road
Woodbury, CT 06798
(203) 982 – 4239

Device Trade Name: Twin Peaks Lumbar Cage

Contact:

Richard Deslauriers, M.D.
CEO

Date Prepared: August 29, 2011

Classification: §888.3080; Intervertebral body fusion device

Class: II

Product Code: MAX

Indications For Use: The Qualgenix Twin Peaks Lumbar Cage is indicated for intervertebral body fusion with autogenous bone graft material in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment. The Qualgenix Twin Peaks Lumbar Cage is to be used with supplemental fixation.

Device Description: The Qualgenix Twin Peaks Lumbar Cage consists of lumbar spinal interbody fusion devices in 20mm and 25mm footprints as well as instrumentation designed specifically for the implantation of these devices. The cage is manufactured from PEEK OPTIMA LT1 polymer. Bone graft is intended to be placed in the middle of the device.

Predicate Device(s): The Qualgenix Twin Peaks Lumbar Cage was shown to be substantially equivalent to previously cleared devices, including the DePuy Spine Lumbar Cages (K081917) SpineArt Juliet Cage (K101710), and Scient'X Tribeca Cage (K080588), and has the same indications for use, design,

and function. For example, the Qualgenix Twin Peaks Lumbar Cage has the same footprint and mechanical equivalence as the cited predicate devices.

Performance Standards: Preclinical testing has been performed per ASTM F2077 (static compression, static torsion, dynamic compression), expulsion testing, and ASTM F2267 (subsidence testing) indicating that the Qualgenix Twin Peaks Lumbar Cage is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Qualgenix
% Richard Deslauriers, M.D.
CEO
87 Carmel Hill Road
Woodbury, Connecticut 06798

APR 18 2012

Re: K112696
Trade/Device Name: Qualgenix Twin Peaks Lumbar Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 8, 2012
Received: March 9, 2012

Dear Dr. Deslauriers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): __K112696_____

Device Name: Qualgenix Twin Peaks Lumbar Cage

The Qualgenix Twin Peaks Lumbar Cage is indicated for intervertebral body fusion with autogenous bone graft material in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment. The Qualgenix Twin Peaks Lumbar Cage is to be used with supplemental fixation.

Prescription Use ___V____ (Part 29 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (29 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112696